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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO.       |
|--|-------------|----------------------|---------------------------|------------------------|
| 09/762,850   | 04/13/2001  | Ulrich Zimmermann    | 113737.6                  | 2752                   |
| 23973 7590 01/03/2008<br>DRINKER BIDDLE & REATH<br>ATTN: INTELLECTUAL PROPERTY GROUP<br>ONE LOGAN SQUARE<br>18TH AND CHERRY STREETS<br>PHILADELPHIA, PA 19103-6996 |             |                      | EXAMINER<br>NAFF, DAVID M |                        |
|  |             |                      | ART UNIT<br>1657          | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>01/03/2008   | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

09/762,850

### Applicant(s)

ZIMMERMANN ET AL.

### Examiner

David M. Naff

### Art Unit

1657

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/13/07 & 10/12/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-42, 52 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-42, 52 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/07 has been entered.

An amendment filed 10/12/07, replacing a non-compliant amendment  
10 of 9/13/07, amended claims 29-32, 34 and 35.

Claims examined on the merits are 29-42, 52 and 56, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.  
15 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with  
20 which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-42, 52 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not  
25 described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate support is not found in the specification for reciting "source material has not been previously processed" (claim 29, bridging lines 6 and 7) when the source material is fresh algae or dried algae, and "pore size of approximately 15  $\mu\text{m}$ " (line 2 of claim 35). These recitations are not found in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-42, 52 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, "fresh algae", "dried algae" and "source material has not been previously processed" are uncertain as to meaning and scope. Being "fresh" is relative and subjective, and "dried algae" is unclear as to when the algae is dried. Since "dried algae" is a processed algae due to drying, it is uncertain as to processing excluded by requiring the source material to not be previously processed. Additionally, the specification indicates (page 7, lines 1 and 19-20) the source material can be commercial alginate. Such commercial alginate results from processing of algae.

In line 2 of claim 32, "said treating of the solution" does not have clear antecedent basis since in claim 29 does not require

treating a "solution". Similarly in claim 33, there is not clear antecedent basis for "the solution" (both occurrences) since claim 29 requires filtering a liquid. A solution is not required in claim 29 until filtering produces a filtrate that is a solution (line 8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-42, 52 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klock et al (AP) in view of Nevins et al (4,954,447) and Yeh (5,489,674).

The claims are drawn to a process of obtaining a highly pure alginate composition. Claim 29 requires steps of (a) treating a fresh or dried algae source that has not been previously processed with a complex forming agent creating a liquid comprising dissolved alginate and solid matter, (b) filtering the liquid to produce a filtrate containing dissolved alginate, (c) precipitating the alginate out of solution, (d) collecting and dewatering the precipitated alginate, and (e) repeating steps (a) to (d) at least once.

Klock et al disclose production of purified alginates suitable for use in immunoisolated transplantation by purifying raw alginates (page 640, right column, line 3, and line 9 of the second paragraph). The process exemplified (page 638 (abstract), paragraph bridging pages 639 and 640, and page 640, left column, beginning with the first full paragraph) involves dissolving commercial alginate (sodium alginate) in water, adding barium chloride to form barium alginate beads, extracting the beads, dissolving the beads in an alkaline EDTA solution to convert the barium alginate to sodium alginate, filtering the resultant solution, precipitating alginate and drying the precipitated alginate.

Nevins et al disclose (column 6, lines 32-35) that repeating purification steps when purifying an enzyme provides greater purity.

Yeh discloses (column 3, lines 58-62) that repeating process steps in purification of a polygalactomannan gum produces greater purity.

The steps of the process of Klock et al are encompassed by the present claims except that the claims require repeating the steps of the process at least once.

It would have been obvious to repeat the purification steps of Klock et al at least once to obtain greater purification as suggested by Nevins et al and Yeh disclosing repeating purification steps of a process to obtain greater purity. When repeating the process steps of Klock et al as suggested by Nevins et al and Yeh, the resulting process is the same as required by claim 29. Treating barium alginate beads with alkaline EDTA (complex forming agent) to form soluble sodium alginate as disclosed by Klock et al (page 640, left column, 6<sup>th</sup> full paragraph) is encompassed by step a) of claim 29 since the barium alginate beads can be considered a "fresh algae" source due to the beads not being the final purified product in the process of Klock et al. Drying the beads before further processing would have been obvious when the beads are desired to be stored before further processing since commercial sodium alginate is in dry form. While the process of Klock et al reacts commercial sodium alginate with barium ion to form the barium alginate beads and then extracts the beads, the beads are still an impure form of alginate that must be further treated with alkaline EDTA to form soluble sodium alginate which is further treated by filtering, dialyzing, precipitating by ethanol and drying. Due to the several purification steps performed by Klock et al after forming the extracted barium alginate beads, the barium

alginate beads are within the scope of "fresh algae" source material, and "dried algae" source material when dried. The present specification fails to contain a definition of "fresh algae" and "dried algae" source materials sufficiently limiting to exclude the

5 fresh and dried algae source material being the barium alginate beads of Klock et al. The specification fails to define the specific form of algae material that is fresh or dried that is "well-suited" (paragraph bridging pages 6 and 7). Commercial alginate is disclosed in the specification as a source material (page 7, lines 1 and 19-20).

10 Commercial alginate can be considered fresh when initially obtained and is normally shipped and sold in dried form. Producing commercial sodium alginate involves isolating algae from the plant and treating it to form sodium alginate. If commercial sodium alginate, which is a processed algae material, can be considered a source material

15 (specification page 7, lines 1 and 19-20) because it is not a final purified product, the barium alginate beads in the process of Klock et al can be considered a fresh algae material relative to the final purified alginate product, even through the beads result from further processing of commercial sodium alginate, since the beads are not the

20 final purified product in the process of Klock et al. If the barium alginate beads of Klock et al were produced as a commercial alginate, and used as a starting material for the steps in Klock et al at page 640, left column, 6<sup>th</sup> complete paragraph, the barium alginate beads



will be a fresh algae source material analogous to commercial sodium alginate.

Steps b)-d) of claim 29 are steps performed in the process of Klock et al. Filtering as in step b), precipitating as in step c) and  
5 collecting and dewatering as in step d) are included in steps carried out by Klock et al (page 640, left column, 6<sup>th</sup> complete paragraph). The final step of drying of Klock et al inherently dewateres.

The alginate composition of dependent claim 52 resulting from the process of claim 29 will inherently be produced when carrying out the  
10 process of Klock et al and repeating the steps at least once for further purification as suggested by Nevins et al and Yeh. The conditions of dependent claims 30-42 and 56 would have been obvious from conditions disclosed by Klock et al.

#### **Conclusion**

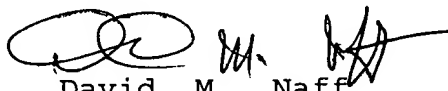
15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,  
20 the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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David M. Naff  
Primary Examiner  
Art Unit 1657

DMN  
15 12/22/07